

Remarks

Claims 35-50 are pending. Claims 1-34 were previously cancelled without prejudice to or disclaimer of the underlying subject matter. Claims 38, 39, 40, 43, 44, 47 and 50 have been amended. Support for the amended claims can be found throughout the specification, for example on page 12, line 12 through page 13, line 18, in the sequence listing, and in the claims as originally filed. Upon entry of these amendments, claims 35-50 will be pending. The specification has been amended at the request of the Examiner to remove alleged embedded hyperlinks and/or other forms of browser-executable code. No new matter enters by way of these amendments.

I. Response to Restriction/Election

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants further acknowledge the finality of the election requirement to a “single nucleotide sequence of the five to be the second transgenic nucleic acid molecule”, but maintain their traversal. Applicants submit that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that “to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide

sequences to be claimed in a single application.” (M.P.E.P., 8th ed., rev. 1, February 2003, Section 803.04). The MPEP further provides that “[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes.” (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Applicants, however, acknowledge and thank the Examiner for rejoining the sequences corresponding to SEQ ID NO: 2, with the instant claims. Thus, sequences SEQ ID NO: 7, 8, 9 and 28 have been rejoined with SEQ ID NO: 2 with the instant claims.

Although Applicants disagree with the election requirement of a single nucleotide sequence of the those to be the second transgenic nucleic acid molecule, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 2, and the corresponding, rejoined, sequences SEQ ID NOs: 7, 8, 9 and 28.

II. Rejection under 35 U.S.C. § 112, first paragraph, Written Description

Claim 50 stands rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was “not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Office Action at pages 2-4. Applicants respectfully traverse this rejection.

More particularly, the Examiner argues that “[t]he claim is directed to encompass nucleic acid sequences that are not limited to SEQ ID NO: 2, 7-9 and 28. Claim 50

encompasses any sequences that are at most described as the 3' – untranslated sequence from the 3' end of the *Pisum sativum* rbcS E9 gene.” *Id.* at page 3. Apparently, the Examiner contends that “as the claim is written the sequence encompassed by the claim extend in both directions from SEQ ID NO: 2, 7-9 and 28 (7-9 and 28 are of SEQ ID NO: 2), and it encompasses sequences of any magnitude and/or content that comprise at least a 3'- untranslated sequence from the 3' end of the *Pisum sativum* rbcS E9 gene.” *Id.* The Examiner concludes that “the claim encompass [sic] an extremely large genus of polynucleotides, wherein the specification’s disclosure of a single sequence of SEQ ID NO: 2 is not representative of this genus.” *Id.*

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventor actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not “describe,” in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims “may be broader than the specific embodiment disclosed in a specification.” *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed.

Cir. 1985), quoting *In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, simply because the claimed nucleic acid sequences may also include sequences from “other species, mutated fragment sequences, allelic variants, splice variants, genomic sequences and so forth” does not require that Applicants describe each and every one of these molecules.

Furthermore, if a person of ordinary skill in the art would, after reading the specification, understand that the inventor had possession of the claimed invention, even if not every nuance, then the written description requirement has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of the claimed invention.

For example, the specification describes gene sequences, corresponding sequences preferred sequences, and so forth of the *Pisum sativum* rbcS E9 gene (see, e.g., specification at page 26, line 1 through page 28, line 14; in the Sequence Listing; and in the claims as originally filed). The specification also describes appropriate hybridization conditions (see, e.g., specification at page 12, line 12 through page 13, line 18); oligonucleotides and primers for obtaining oligonucleotides (see, e.g., specification at page 9, line 22 through page 10, line 24 and in the sequence listing); oligonucleotides that hybridize to 3' untranslated regions (see, e.g. specification at page 21, line 17 through page 22, line 4 and in the sequence listing); and expression detection and quantitation methods (see, e.g., specification at page 28, line 15 through page 37, line 9). Despite the numerous variations described for the nucleic acid molecules in the present specification,

the Examiner argues that “the disclosure of a single sequence of SEQ ID NO: 2 is not representative of this genus.” Office Action at page 3.

The written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...i.e., complete or partial structure, other physical and or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). (quoting from Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001)). Applicants have satisfied that test for written description. For example, Applicants have disclosed a structural feature, the nucleotide sequence of SEQ ID NO: 2. This feature provides a basis for each and every nucleic acid molecule in the claimed genus. Moreover, it distinguishes the members of the claimed genus from non-members.

The Examiner further alleges that the “claim language ‘hybridize’ does not present the conditions claimed (high, moderate, or low stringency); thus encompassing sequences that again correspond to sequences from other species, mutated fragment sequences, allelic variants, splice variants, genomic sequences and so forth.” *Id.* The Examiner again alleges that the “specification provides insufficient written description to support the genus encompassed by the claim.” *Id.* Applicants respectfully disagree, however, to facilitate prosecution claim 50 has been amended herein to recite “stringent

hybridization” conditions. Support for such amendments is found in the specification, for example at page 12, line 12 through page 13, line 18.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, pending claim 50 is supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed. Reconsideration and withdrawal are respectfully requested.

III. Rejections under 35 U.S.C. §112, Second Paragraph

The Examiner has rejected claims 35-49 under 35 U.S.C. § 112, second paragraph, as being indefinite. Office Action at page 5. Applicants respectfully disagree. Applicants respectfully point out that the claims are to be read in light of the specification. *See in re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The test for determining whether terms in a given claim are indefinite is whether one skilled in the art would understand what is claimed. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991), *cert denied*, 112 S.Ct. 169 (1991). A person of ordinary skill in the art would understand the metes and bounds of the claims read in light of the disclosure of the specification.

The Examiner contends that “[c]laim 35 is vague and indefinite due to the lack of clarity in the steps of methodology due to the claim language and arrangement of the claim language.” Office Action at page 5. In particular, the Examiner argues that “[i]t is unclear whether the ‘method comprising’ is directed to merely to mRNA of condition (b) or is directed to both condition (a) and (b).” *Id.* Applicants respectfully disagree.

A grammatically consistent interpretation of the claim as amended would relate the phrase “said method” back to the phrase “[a] method to detect expression of a first transgenic nucleic acid molecule” in the preamble. Thus, the skilled artisan would understand that the steps of the claimed method are directed to methods of detecting expression of a first transgenic nucleic acid molecule in a sample having either condition (a) or condition (b). Based on the foregoing, Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

The Examiner also alleges that claim 35 “is vague and indefinite due to the lack of clarity of the method steps that perform the method claimed.” Office Action at page 5. More particularly, the Examiner alleges that “[i]t is unclear whether the method claimed is directed to detecting DNA that corresponds to the 2nd transgenic nucleic acid; detecting the expression of the 2nd transgenic nucleic acid; detecting the presence or absence of the 1st transgenic nucleic acid molecule; or detecting the expression of 1st transgenic nucleic acid molecule.” *Id.* Applicants respectfully disagree.

Applicants respectfully assert that the claimed method is readily understandable by one of skill in the art to be directed to methods of detecting expression of a first transgenic nucleic acid, particularly when considered in the context of claim 35 as a whole and the specification. *See, e.g.,* Specification at page 4, line 5 through page 5 line 14 and page 37, line 13, *et seq.* (Examples 1-3). In particular, claim 35 recites “[a] method to detect expression of a first transgenic nucleic acid molecule,” and “whereby said hybridizing indicates the expression of said first transgenic nucleic acid molecule in

a sample.” Applicants therefore respectfully request reconsideration and withdrawal of the indefiniteness rejection of claim 35 under 35 U.S.C. § 112, second paragraph.

The Examiner further alleges that “[c]laims 40, 43 and 44 are vague and indefinite due to the lack of clarity of the terms ‘substantial identity’ (claims 43 line 2), and ‘substantially identical’ (claim 44 line 2; claim 40 line 2).” Office Action at page 6. The Examiner alleges that this language is indefinite because “the metes and bounds of the claim are unclear because the specification has not defined how much identity a nucleic acid must have to be considered ‘substantially identical.’” *Id.* Applicants respectfully disagree. However, to facilitate prosecution, claims 40, 43 and 44 have been amended to remove the terms “substantial identity” and “substantially identical.” Applicants therefore respectfully request reconsideration and withdrawal of the indefiniteness rejection of claims 40, 43 and 44 under 35 U.S.C. § 112, second paragraph.

The Examiner also alleges that “[c]laim 47 is vague and indefinite due to the lack of clarity of the claim language (emphasis added) ‘said at least one oligonucleotide comprises a primer *pair and a probe* designed to hybridize to a [/any] nucleic acid molecule in a 5’ nuclease assay’ lines 1-2.” Office Action at page 7 (emphasis Examiner’s). The Examiner argues that “[a]s written, the claim appears to require that the oligonucleotide be made up of all three of these sequences as one long sequence – the forward primer, the reverse primer, and the probe – and hybridize to any nucleic acid molecule.” *Id.* Applicants respectfully disagree.

The meaning of the phrase “said at least one oligonucleotide comprises a primer pair and a probe designed to hybridize to a nucleic acid molecule in a 5’ nuclease assay”

is clear when read in light of the specification. For example, the specification describes 5' nuclease assays. *See, e.g.*, specification at page 31, line 23 to page 32, line 12. Furthermore, one of ordinary skill in the art would understand that a 5' nuclease assay usually involves at least one oligonucleotide which comprises a primer pair and a probe designed to hybridize to a nucleic acid molecule. Thus, the phrase "said at least one oligonucleotide comprises a primer pair and a probe designed to hybridize to a nucleic acid molecule in a 5' nuclease assay", as used in the claims, has been defined in the specification and would be understood to one of ordinary skill in the art given the disclosure in the specification. To facilitate prosecution, however, claim 47 has been amended to recite "said at least one oligonucleotide comprises a pair of oligonucleotide primers and an oligonucleotide probe" Moreover, also to facilitate prosecution, claim 47 has been amended to recite "a probe designed to hybridize to said second transgenic nucleic acid molecule in a 5' nuclease assay." Based on the foregoing, Applicants assert that the rejection under 35 U.S.C. § 112, second paragraph, is improper with respect to claim 47 and should be withdrawn.

Accordingly, for at least the foregoing reasons, the rejection of claims 35-49 under 35 U.S.C. § 112, second paragraph is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

IV. Rejection under 35 U.S.C. §102

A. Miyamoto et al., Plant Molecular Biology Reporter, June 2000

Claims 35, 36, 40-42 and 44-47 stand rejected under 35 U.S.C. 102(a) as allegedly anticipated by Miyamoto *et al.* The Examiner asserts that:

Miyamoto et al. teaches a method of quantitating very low levels of mRNA expression of a transgenic nucleic acid (beta-glucuronidase: GUS) (*claim 36*) (p. 101, *Introduction*, 1st paragraph). The method of quantitation is carried out by RT-PCR (*claim 41*), specifically quantitative RT PCR (*claim 42*) (p. 102, 2nd paragraph). Page 102 (*Primers and a fluorogenic probe for RT-PCR*) describes a primer pair and a probe for the oligonucleotides utilized in the method.

Office Action at page 7.

“It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention.” *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, “an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.” *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). Whatever else Miyamoto et al. teaches, it does not disclose a method to detect the expression of a first nucleic acid molecule in sample comprising providing a complementary DNA of a mRNA transcribed from a second transgenic nucleic acid molecule. Absent a teaching of each and every element of the claims, the reference cited by the Examiner does not anticipate claims 35, 36, 40-42 and 44-47 and the rejection should be reversed.

Accordingly, for at least the foregoing reasons, the rejection of claims 35, 36, 40-42 and 44-47 under 35 U.S.C. § 102(a) is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

B. Hamilton et al., Gene, 1997

Claims 35, 40, 41, 47 and 49 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Hamilton et al. In support of this rejection, the Examiner asserts that: “Hamilton demonstrates the expression of transgenes in a BIBAC vector (p. 113, 2nd

column, 3rd paragraph), wherein a successful transfection into the host plant is determined based upon the following transgenic nucleic acids: *sacB* gene, GUS-NPTII gene (beta-glucuronidase – neomycin phosphotransferase II), and the HYP gene (hygromycin phosphotransferase).” Office Action, at page 8.

This rejection is respectfully traversed for at least the reasons which follow. As argued above, it is well established that to anticipate a claim, a reference must disclose every element of the claim. *Verdegaal Bros. v. Union Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989).

Applicant respectfully submits that the Hamilton *et al.* disclosure does not include all of the limitations of the present claims. Whatever else Hamilton *et al.* teaches, it does not disclose a method to detect the expression of a first nucleic acid molecule in sample employing hybridizing a complementary DNA of an mRNA from a second transgenic nucleic acid molecule with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid molecule where the hybridization indicates the expression of the first transgenic nucleic acid molecule in a sample. Absent a teaching of each and every element of the claims, the reference cited by the Examiner does not anticipate claims 35, 36, 40-42 and 44-47 and the rejection should be reversed.

Accordingly, for at least the foregoing reasons, the rejection of claims 35, 36, 40-42 and 44-47 under 35 U.S.C. § 102(a) is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

V. Rejection under 35 U.S.C. § 103

Claims 35-50 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hunt *et al.* (*DNA*, 1988), taken in combination with Freeman *et al.* (*BioTechniques*, 1999). This rejection is respectfully traversed for at least the reasons which follow.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art, and not be based on applicant's disclosure. See M.P.E.P. §§2143.01 and 2143.03.

In a proper obviousness determination, the changes from the prior art must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the claimed invention. See *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). This includes what could be characterized as simple changes. See, e.g., *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (Although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down.).

Only when the prior art teaches or suggests the claimed invention does the burden fall on the applicant to rebut that *prima facie* case. See *In re Dillon*, 16 USPQ2d 1897,

1901 (Fed. Cir. 1990) (in banc), *cert. denied*, 500 U.S. 904 (1991). However, a *prima facie* case of obviousness may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention.

The Examiner argues that Hunt *et al.* discloses “the transformation of a tobacco plant with a plasmid carrying the 3’ noncoding strand of the pea rbcS-E9 3’ region (claims 37, 38) which aligns 99.5% with SEQ ID NO: 2 (a 637 bp sequence) from residue 1-633 (claim 39), and a desired transgene pAH10 (figure 2A).” Office Action at page 10. Hunt *et al.*, however, “does not teach the amplification by PCR or RT-PCR, quantitative and competitive RT-PCR, the primers utilized for the amplification as required by claims 36, 41, 42, 47, 48 and 50.” Office Action at page 11.

The Examiner argues that “Freeman teaches the benefits of PCR, specifically utilizing quantitative RT-PCR, both competitive and non-competitive (pp. 116-117) to quantify mRNA (claims 36, 41, 42).” Office Action at page 11. Applicants respectfully submit that the cited references do not render the present independent claims obvious, since the claims are not taught nor suggested by the cited references. The cited references do not disclose or suggest a method to detect the expression of a first transgenic nucleic acid molecule in a sample comprising amplifying a complementary DNA from an mRNA from a second transgenic nucleic acid molecule and hybridizing the cDNA with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid molecule where hybridizing indicates the expression of the first transgenic nucleic acid molecule in a sample.

The Examiner has stated that “it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to improve the detection method of Hunt *et al* and further modify the mRNA expression analysis to utilize quantitative RT-PCR which includes amplification along with primers and probes designed for quantitative RT-PCR as per the teachings of Freeman *et al.* because Freeman teaches that quantitative RT-PCR provides increased sensitivity in mRNA detection.”

Office Action at page 11.

Initially, Applicants respectfully disagree with the Examiner’s characterization of the art. By way of example, the Examiner asserts that “it would have been *prima facie* obvious ... to improve the detection method of Hunt, *et al....*” In this regard, Applicants note that nowhere does Hunt *et al.* disclose or suggest a method for detecting the expression of a first transgenic nucleic acid molecule. Hunt *et al.* does, however, provide an identification and characterization of cryptic polyadenylation sites in the 3’ region of a pea *rbcS-E9* gene. As such, it is respectfully submitted that the Examiner’s conclusion of obviousness is based on improper reasoning and a misinterpretation of the art.

Even assuming *arguendo* that the combination is proper, the combination does not render the claimed invention obvious. Whatever else Hunt *et al.* and Freeman *et al.* disclose, they do not teach or suggest a method to detect the expression of a first transgenic nucleic acid molecule in a sample by hybridizing a complementary DNA of mRNA transcribed from a second transgenic nucleic acid molecule with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid molecule where the hybridization indicates the expression of the first transgenic nucleic acid

molecule in the sample. The Examiner has not pointed to any specific suggestion in any of the cited references to reach the presently claimed invention. It is impermissible hindsight to find it obvious for one skilled in the art to combine the cited references to reach the invention in the present application absent some suggestion or motivation in the cited references. Therefore, it would not be obvious to one skilled in the art, from reading Hunt *et al.* and Freeman *et al.* that one could obtain the methods of the present invention.

Moreover, the skilled artisan would not turn to Hunt *et al.* to solve the problem of detecting the expression of a first transgenic nucleic acid molecule. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). *See also In re Deminski*, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); *In re Clay*, 966 F.2d 656, 23 USPQ2d 1058 (Fed. Cir. 1992). Applicants submit that Hunt *et al.* is not analogous art. First, the Hunt *et al.* reference is not in the Applicant's field of endeavor. The Hunt *et al.* reference describes the identification of "a number of discrete, cryptic polyadenylation sites located downstream from the previously-determined poly(A) sites of" the 3' region of the pea *rbcS-E9* gene. This is a different field of endeavor from the methods for detecting the expression of a first transgenic nucleic acid molecule in a sample by hybridizing a complementary DNA of mRNA transcribed from a second transgenic nucleic acid molecule with at least one oligonucleotide designed to hybridize to the second transgenic

nucleic acid molecule where the hybridization indicates the expression of the first transgenic nucleic acid molecule in the sample.

Nor is Hunt *et al.* reasonably pertinent to the particular problem that the present inventors faced. Hunt *et al.* addresses the “sequence requirements for the polyadenylation of mRNAs in plants.” Hunt, page 329. A person faced with the problem of detecting the expression of a first transgenic nucleic acid molecule would not find the teachings of Hunt pertinent.

Moreover, Freeman *et al.* does not make up what Hunt lacks. The Examiner argues that Freeman *et al.* “teaches designing primers for use in [quantitative RT-PCR assays] to be gene specific or non-specific however if specific then it ‘increases specificity and decreases background associated with other types of primers.’” Office Action at page 11. Applicants submit that Freeman *et al.* further describe non-specific primers as “[r]andom hexamer primers [containing] all possible nucleotide combinations of a 6-base oligonucleotide and bind to all RNAs present,” and “oligonucleotides solely of deoxythymidine residues [oligo(dT)].” The cited reference does not disclose a method for detecting the expression of a first transgenic nucleic acid molecule in a sample by hybridizing a complementary DNA of mRNA transcribed from a second transgenic nucleic acid molecule with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid molecule where the hybridization indicates the expression of the first transgenic nucleic acid molecule in the sample.

In sum, the Examiner’s conclusion of obviousness is based on improper hindsight reasoning. “Impermissible hindsight must be avoided and the legal conclusion must be

reached on the basis of the facts gleaned from the prior art.” M.P.E.P. § 2142 at 2100-124. No suggestion to modify the cited references has been found in the cited references or pointed out to Applicant from the general knowledge of one of ordinary skill in the art. In addition, no indication for Hunt *et al.* teaching the claimed method is provided. For at least these reasons, the Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, as required by 35 U.S.C. § 103.

Accordingly, for at least the foregoing reasons, the rejection of claims 35-50 under 35 U.S.C. § 103 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

VI. Objections to the Specification

The specification has been objected to for purportedly containing “embedded hyperlinks and/or other form of browser-executable code.” Office Action at page 12.

Applicants have amended the specification to replace the phrase “http://www” with “available on the worldwide web at.” In addition, the underlining has been removed from the website citation. The citation of a website in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application.

In addition, the Examiner alleges that “the specification is objected to due to the inconsistency in the specification for the description as to that which describes SEQ ID NO: 2 and 3.” Office Action at page 12. In particular, the Examiner notes that Table 1 refers to SEQ ID NO: 3 is an NPTII gene, while Example 1 describes SEQ ID NO: 3 as the 3’ untranslated region of *Pisum sativum* rbcS gene. *Id.* Applicants have amended the specification to correct the typographical error in Example 1.

In light of these remarks and amendments, Applicants respectfully request withdrawal of this objection to the specification.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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